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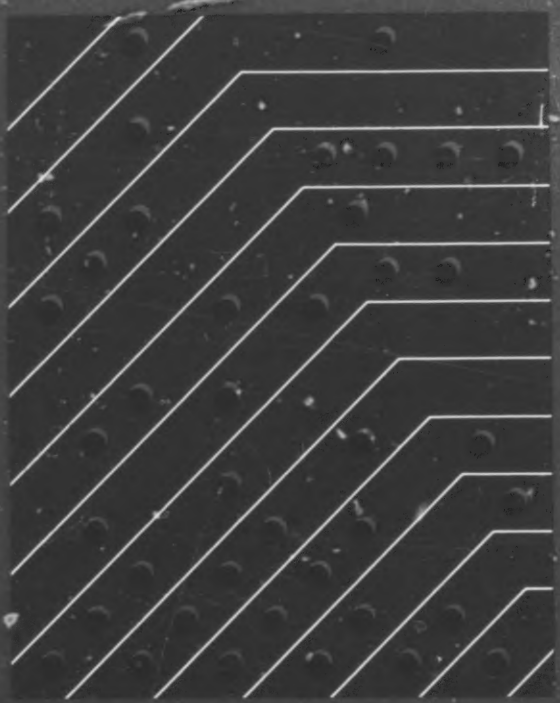
National Cancer Institute

Investigational Drug Accountability Record

Form and Instructions



U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

HE 20.3185:

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Form Approved
OMB No. 0925-0240
Expires 6/30/91

National Cancer Institute

Investigational Drug Accountability Record

Form and Instructions

Drug Management and Authorization Section
Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Dear Investigator:

I am providing you with the following information on the subject of accountability of investigational agents. The regulations of the Food and Drug Administration (FDA) require investigators to establish a record of the receipt, use, and disposition of all investigational agents. The National Cancer Institute (NCI), as a sponsor of investigational drug trials, has the responsibility to assure the FDA that systems for drug accountability are being maintained by investigators in its clinical trials program. In order to help you fulfill these requirements, we have developed a standardized investigational drug accountability report form which must be used for all investigational agents supplied by the NCI. This form has been designed to account for drug inventories and usage by protocol.

We would like to take this opportunity to call your attention to certain aspects of investigational drug usage. Any physician who receives and administers an investigational agent supplied by NCI must be registered with the NCI by filing a form FDA-1572. Investigational drugs provided by NCI to a registered investigator are the direct responsibility of that investigator. Secondary distribution to other registered physicians does not relieve the physician to whom the original shipment was made from his/her responsibility. For your protection, as a general rule the NCI discourages secondary shipment. Direct shipment from NCI to satellites and affiliates is preferred and highly recommended.

We would also like to remind you that investigational drugs should be kept in a secure place (e.g., a pharmacy or physician's office). In addition, investigational drugs supplied by the NCI must not be used except for those protocols for which drug has been ordered.

The drug accountability records must be available to NCI upon request and will be reviewed as a part of the NCI site-visit monitoring program.

In summary we are asking you:

1. To order drug for the specific protocols for which it will be used.
2. To establish a protocol-oriented drug accountability system using the enclosed forms, and
3. To maintain records of the drug accountability system and have them available for NCI site visits.

Sincerely,

Clarence L. Fortner

Clarence L. Fortner
Head, Drug Management and
Authorization Section
Investigational Drug Branch, CTEP
Division of Cancer Treatment

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National Cancer Institute

PAGE NO. _____

CONTROL RECORD ☐

SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution

Protocol No. (NCI)

Drug Name, Dose Form and Strength

Protocol Title

Dispensing Area

Investigator

Line No	Date	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1								
2								
3								
4								
5								
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National Cancer Institute Investigational Drug Accountability Record

General Instructions

These are the instructions for the National Cancer Institute's (NCI) Investigational Drug Accountability Record form (NIH-2564). Several examples that will clarify how the form should be used are also included.

You will need one form for each investigational drug used on each research protocol. If a protocol contains more than one investigational drug, a separate accountability form should be used. A separate drug accountability form should also be maintained for each different strength or dosage form of the particular drug being used.

The form has been designed to be used at each location at which drug is stored for patient administration, i.e., main pharmacy, satellite pharmacy, physician's office or other dispensing areas.

The form is also designed to accommodate both dispensing accountability and other types of drug transactions (receipts, returns, broken vials, etc.).

Instructions for Investigational Drug Accountability Record Form (NIH-2564)

■ **The uper portion of the form requires information related to the specific protocol** (Figures 1 and 2)

Control Location

Figure 1 -
Protocol Related Section of the Form: Control Location

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National Cancer Institute

PAGE NO. 1

CONTROL RECORD ☒

SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution	ACME Hospital	Protocol No. (NCI)	12345
Drug Name, Dose Form and Strength	Act - 16 injection 10 mg		
Protocol Title	ANLL	Dispensing Area	Central Pharmacy
Investigator	T. Thompson		

Record the name of institution or other identifier; e.g., private physician's office, medical oncology pharmacy, etc., to which the drug is shipped by the NCI. The identifier in the sample form is the Acme Hospital.

Record abbreviated protocol title (e.g., ANLL on the sample).

Record the name of the investigator in whose name the drug is ordered from NCI (Dr. T. Thompson on the sample).

Record drug name, dosage form (tablet, injection, etc.), and strength. Note: **Use a separate form for each dosage form and strength.** The sample form is used for Act-16, 10 mg. for injection. If another drug or another dose form is used on protocol 12345, a separate Investigational Drug Accountability Record form must be maintained for each.

Record the NCI assigned protocol number (protocol -12345 in our sample); you may add your institutional protocol number. (If the protocol is a cooperative group protocol, the NCI number and the cooperative group number will be the same.)

Record the page number consecutively on the forms for each drug used on the protocol.

A check in the control record box indicates that the form is being used in the area where the initial shipment of the drug is stored. If the investigational drug is dispensed only from this area, the control record will be the only form used.

Record the dispensing area, i.e., central pharmacy.

Satellite Location

The satellite record is to be used when drugs are moved to other areas away from the control area or primary storage area; e.g., satellite pharmacies within or outside the primary institution, physician's office, regional hospitals, etc. This sample is prepared for a satellite location (Figure 2).

The satellite record form will normally contain the same information as the control record form with the exception of the Dispensing Area and a check in the Satellite Record Box.

Figure 2 -
Protocol Related Section of the Form: Satellite Location

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National Cancer Institute

PAGE NO. 1

CONTROL RECORD ☐

*SATELLITE RECORD ☒

Investigational Drug Accountability Record

Name of Institution: ACME Hospital

*Protocol No. (NCI): 12345

Drug Name, Dose Form and Strength: Act - 16 injection 10 mg

Protocol Title: ANLL

*Dispensing Area: Dr. R. Jone's office

Investigator: T. Thompson

Record the NCI assigned protocol number (protocol #12345 on our sample); you may add your institution protocol number. (If the protocol is a cooperative group protocol the NCI number and the cooperative group number will be the same.)

A check in the satellite record box indicates that the drug has been moved away from the control location.

Record the dispensing area, i.e., Dr. R. Jones' office.

Note: **If more than one investigator from the same institution orders a drug for the same protocol, separate records must be maintained. If you use more than one page, the above information must be recorded on each page.**

■ **The lower portion of the form is designed to record drug transactions whether using the control and/or satellite record. The form can be used for recording dispensing to individual patients, as well as for other transactions such as drug receipts, returns from satellite pharmacies, etc.**

Patient Dispensing Accountability

When using the form to record dispensing to patients, the following information should be recorded (Figure 3).

Figure 3
Sample of Patient Dispensing Accountability

Line No.	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward / Balance 0	Manufacturer and Lot No.	Recorder's Initials
1	1-1	Received from NCI			100	100	AXEL 123	CF
2	1-2	J.J.	45324	54mg	6	94	AXEL 123	CF

Dose dispensed

Recorder's initials

Patient's I.D. number (e.g., patient's hospital number)

Manufacturer and lot number

Patient's initials

Balance forward is amount from previous page, will be zero on page 1.

Date of dispensing

Balance of drug remaining in inventory after dispensing

Quantity dispensed (specify tablets, vials etc.)

Accountability for Drug Transactions Other than Patient Dispensing

The form must be used to record the following and similar transactions:

- **1. drug receipt from NCI;**
- **2. drug moved to satellite dispensing areas;**
- **3. drug returns to NCI or to the control location.**

Such transactions should be recorded utilizing the spaces across the line under the columns entitled Patient's Initials, Patient's I.D. Number, and Dose (Figures 4-7). The following information should be recorded according to the various transactions.

1. Drug Receipts from NCI (Figure 4)

Figure 4 -
Drug Received from NCI By Control

Line No	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward 0 Balance	Manufacturer and Lot No	Recorder's Initials
1	1-1	Received from NCI			100	100	AXEL 123	CF

Record: Date

Quantity received

Recorder's initials

Manufacturer and lot number

Add quantity received to previous balance (if this is the first receipt, previous balance is zero)

■ **2. Drugs moved to satellites must be recorded on both the control and satellite record** (Figures 5 and 6).

Drugs moved to satellite (to be recorded on control record only). (Figure 5)

Figure 5 -
Drug Moved to Satellite from Control

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PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution: ACME Hospital
Protocol No. (NCI): 12345
Drug Name, Dose Form and Strength: Act - 16 injection 10 mg
Protocol Title: ANLL
Dispensing Area: Central Pharmacy
Investigator: T. Thompson

Line No.	Date 1989	Patient's Initials	Patient's ID Number	Dose	Quantity Dispensed or Received	Balance Forward 0 / Balance	Manufacturer and Lot No.	Recorder's Initials
1	1-1	Received from NCI			100	100	AXEL 123	CF
2	1-2	J.J.	45324	54mg	6	94	AXEL 123	CF
3	1-2	Moved to Dr. R. Jones			20	74	AXEL 123	CF

Record: Date
Name of investigator receiving the drug at satellite
Quantity moved
Subtract from balance
Manufacturer and lot #
Recorder's initials

Drugs received by satellite (to be recorded on satellite record only). (Figure 6)

Figure 6 -
Drug Received From Control by Satellite

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National Cancer Institute

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CONTROL RECORD ☐
SATELLITE RECORD ☒

Investigational Drug Accountability Record

Name of Institution: ACME Hospital
Protocol No. (NCI): 12345
Drug Name, Dose Form and Strength: Act - 16 injection 10 mg
Protocol Title: ANLL
Dispensing Area: Dr. R. Jones' Office
Investigator: T. Thompson

Line No	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward 0 / Balance	Manufacturer and Lot No	Recorder's Initials
1.	1-2	Received from T. Thompson			20	20	AXEL 123	R.J.

Name of investigator sending drug from control location
Quantity moved
Recorder's initials
Record: Date
Manufacturer and lot number
Add to balance

Note: **For initial shipments to a satellite dispensing location, a satellite record form should be prepared at the control location and included with the drug shipment. The receiving investigator should place his/her initials in the "Recorder's Initial" block indicating the drug was received.**

3. Drug returns, are recorded as shown in Fig. 7. The same accounting procedure is used whether returning drug from a satellite to a control or from a control to NCI. Figure 7 is an example of a return from a satellite to a control.

Figure 7 -
Drug Returns

Line No	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward 0 / Balance	Manufacturer and Lot No.	Recorder's Initials
1	1-2	Received from T. Thompson			20	20	AXEL 123	R.J.
2	1-3	A.B.	452	19mg	2	18	AXEL 123	R.J.
3	1-4	J.A.	245	10mg	1	17	AXEL 123	R.J.
4	1-8	Returned to ACME Hospital			17	0	AXEL 123	R.J.
5								
6	Returned completed record to							
7	Dr. T. Thompson - ACME Hospital							
8			Dr. Robert Jones					
9								

Record: Date

Manufacturer and lot number

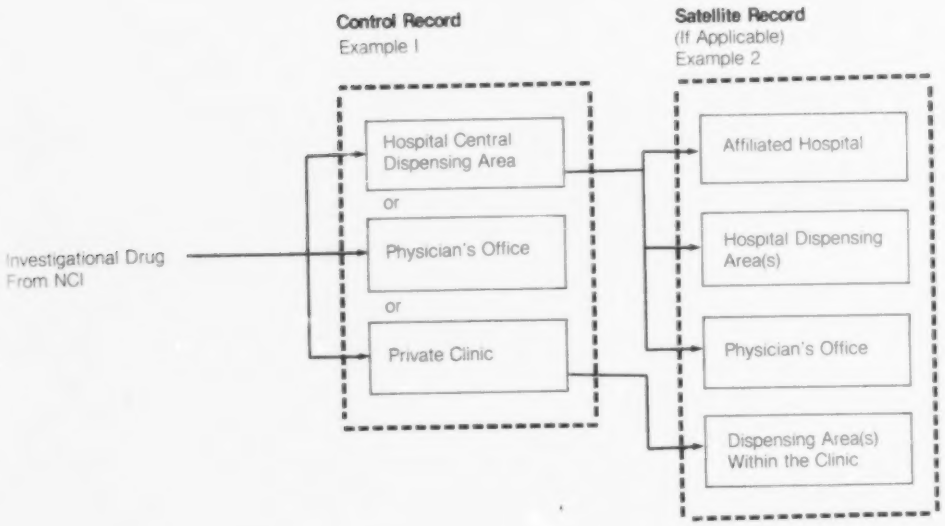
Recorder's initials

Subtract from balance

Quantity returned (specify tablets, vials, etc.) to NCI or control

Instructions for NCI'S Investigational Drug Accountability Record

Flow Diagram for Control and Satellite Records



For example, NCI sends 100 vials of ACT-16 to Dr. T. Thompson at ACME Hqspital under protocol 12345.

Example 1

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Investigational Drug Accountability Record

CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution: ACME Hospital | Protocol No. (NCI): 12345

Drug Name, Dose Form and Strength: Act - 16 injection 10 mg

Protocol Title: ANLL | Dispensing Area: Central Pharmacy

Investigator: T. Thompson

Line No.	Date 1989	Patient's Initials	Patient's ID Number	Dose	Quantity Dispensed or Received	Balance Forward: 0 / Balance	Manufacturer and Lot No.	Recorder's Initials
1	1-1	Received from NCI			100	100	AXEL 123	CF
2	1-2	J.J.	45324	54 mg	6	94	AXEL 123	CF
3	1-2	Moved to Dr. R. Jones			20	74	AXEL 123	CF
4	1-3	Moved to O.P.D.			30	44	AXEL 123	CF
5	1-4	Returned to NCI			20	24	AXEL 123	CF
6	1-8	Received from Dr. R. Jones			17	41	AXEL 123	CF
7	1-9	Received from NCI			100	141	AXEL 123	CF
8	1-10	A.B.	45270	18 mg	2	139	AXEL 123	CF
9	1-10	A.B.	45270	18 mg	2	137	AXEL 123	CF
10	1-11	B.C.	72450	22 mg	3	134	AXEL 123	CF

Dr. Thompson moves 20 vials of Act-16 to his affiliate, Dr. Robert Jones.

Example 2

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National Cancer Institute

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Investigational Drug Accountability Record

CONTROL RECORD ☐
SATELLITE RECORD ☒

Name of Institution: ACME Hospital | Protocol No. (NCI): 12345

Drug Name, Dose Form and Strength: Act - 16 injection 10 mg

Protocol Title: ANLL | Dispensing Area: Dr. Robert Jones' Office

Investigator: T. Thompson

Line No.	Date 1989	Patient's Initials	Patient's ID Number	Dose	Quantity Dispensed or Received	Balance Forward: 0 / Balance	Manufacturer and Lot No.	Recorder's Initials
1	1-2	Received from T. Thompson			20	20	AXEL 123	R.J.
2	1-3	A.B.	462	19mg	2	18	AXEL 123	R.J.
3	1-4	J.A.	245	10mg	1	17	AXEL 123	R.J.
4	1-8	Returned to ACME Hospital			17	0	AXEL 123	R.J.
5								
6		Returned completed record to						
7		Dr. T. Thompson, ACME Hospital						
8								
9				Dr. Robert Jones				
10								

Instructions for NCI's Investigational Drug Accountability Record

Overview

Enter the NCI-assigned protocol number; institutional number optional. If protocol is a cooperative group protocol the group number and NCI number will be the same.
Enter area from which the drug is **actually dispensed** (e.g., Medical Oncology Pharmacy).
Number pages sequentially for each drug strength/form used on the protocol.
Check **Control** if you receive the drug directly from NCI; **Satellite** if drug is moved to you from another area.
This portion of the form is to be completed by the responsible individual at the institution which receives the drug from NCI. When drug is moved to a different dispensing area, this portion is completed at the institution which received the drug from NCI and the form must accompany the initial move of a particular drug under a protocol.
Entry must show the name of the institution or other identifier (e.g., physician's office) receiving the drug **directly from NCI**
Self-explanatory.
Protocol title may be truncated if necessary.
Show only the name of the investigator **in whose name the drug was ordered from NCI.**
Balance carried from previous page, will be zero on page one.
When drug is moved to other dispensing areas (e.g., physician's office) this portion of the form is to be filled out by the person receiving the drug. The completed record and unused drug must be returned to the investigator who originally received the drug from NCI.
Use this section for patient dispensing records as well as for other drug transactions.
A reproducible, perforated copy of this form appears on page 21.
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Investigational Drug Accountability Record
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐
Name of Institution
Protocol No. (NCI)
Drug Name, Dose Form and Strength
Protocol Title
Dispensing Area
Investigator
Line No
Date
Patient's Initials
Patient's I.D. Number
Dose
Quantity Dispensed or Received
Balance Forward
Balance
Manufacturer and Lot No.
Recorder's Initials
1
2
3
4
5
6
7
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NIH-2564
9-85

Transfer Investigational Drug Form

General Instructions

These are the general instructions for the Transfer Investigational Drug Form. Drug(s) may be permanently transferred by an investigator from a completed National Cancer Institute (NCI) protocol to another active NCI approved protocol within the same institution or office for only two reasons.

1. When an NCI approved protocol is completed and no additional drug(s) is needed.
2. When a drug ordered for an individual patient on Special Exception (compassionate) protocol is no longer required for the patient.

These are the only reasons under which investigational drugs may be permanently transferred. This drug transfer information will become a part of the NCI investigational drug accountability record.

Instructions

I. The following information must be recorded:

a. Record the name and NCI registry number of the investigator transferring the drug, including the address and the date of the transfer.

b. Check the box marked either "Completed Protocol" or "Unused Drug Obtained for Special Exception Protocol" on the form.

c. Record the name and NCI registry number of the investigator receiving the drug.

d. Use the lower portion of the form to record the protocol and drug information as follows:

1. protocol number for which the drug was received;
2. protocol number to which the drug is being transferred;
3. NSC number of the drug;
4. drug name;
5. strength and formulation of the drug;
6. quantity being transferred;
7. manufacturer;
8. lot number.

e. Record the name and telephone number if the person making the transfer is not the investigator who ordered the drug from NCI.

II. Return this completed Transfer Investigational Drug Form to:

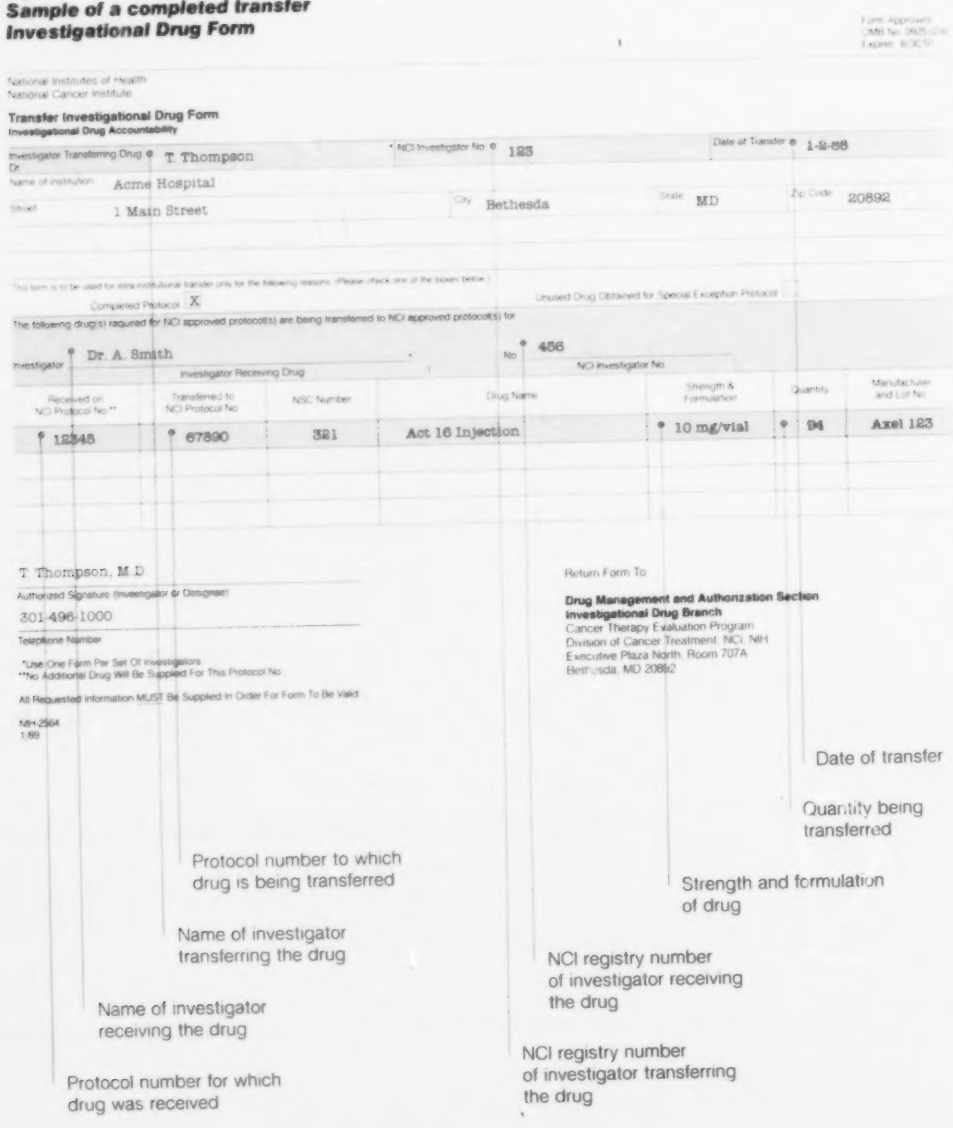
Drug Management and Authorization Section, IDB, CTEP
Division of Cancer Treatment, NCI, NIH
Executive Plaza North, Room 707A
Bethesda, Maryland 20892

■ **Drug transferred from completed protocols must be recorded on the Transfer Investigational Drug Form (Figure 8), the completed Protocol Drug Accountability Record (Figure 9), and the active Protocol Drug Accountability Record (Figure 10).**

■ Drugs Transferred to another active protocol (Figure 8)

This form is used to record intra-institutional transfers of drugs from completed protocols to other active protocols.

Figure 8
Sample of a completed transfer Investigational Drug Form



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National Institutes of Health
National Cancer Institute

Transfer Investigational Drug Form
Investigational Drug Accountability

Investigator Transferring Drug * Dr. T. Thompson | NCI Investigator No * 123 | Date of Transfer * 1-2-88

Name of Institution: Acme Hospital

Street: 1 Main Street | City: Bethesda | State: MD | Zip Code: 20892

This form is to be used for intra-institutional transfer only for the following reasons. (Please check one of the boxes below.)

Completed Protocol: X | Unused Drug Obtained for Special Exception Protocol:

The following drug(s) required for NCI approved protocol(s) are being transferred to NCI approved protocol(s) for

Investigator * Dr. A. Smith | No * 456
Investigator Receiving Drug | NCI Investigator No.

Received on NCI Protocol No.**	Transferred to NCI Protocol No.	NSC Number	Drug Name	Strength & Formulation	Quantity	Manufacturer and Lot No.
* 12345	* 67890	321	Act 16 Injection	* 10 mg/vial	* 94	Axel 123

T. Thompson, M.D.
Authorized Signature (Investigator or Designee)

301-496-1000
Telephone Number

*Use One Form Per Set Of Investigators
**No Additional Drug Will Be Supplied For This Protocol No.

All Requested Information MUST Be Supplied In Order For Form To Be Valid.

NIH-2564
1-89

Return Form To:

Drug Management and Authorization Section
Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment, NCI, NIH
Executive Plaza North, Room 707A
Bethesda, MD 20892

Date of transfer

Quantity being transferred

Protocol number to which drug is being transferred

Strength and formulation of drug

Name of investigator transferring the drug

NCI registry number of investigator receiving the drug

Name of investigator receiving the drug

NCI registry number of investigator transferring the drug

Protocol number for which drug was received

A reproducible, perforated copy of this form appears on page 23.

■ **The Drug Accountability Form is used to record drug transfers from a completed protocol** (Figure 9).

Figure 9
Drug transferred from a completed protocol.

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National Cancer Institute

PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution: Acme Hospital
Protocol No. (NCI): *12345
Drug Name, Dose Form and Strength: Act 16 Injection
Protocol Title: ANLL
Dispensing Area: Central Pharmacy
Investigator: T. Thompson

Line No	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward 0 / Balance	Manufacturer and Lot No	Recorder's Initials
1	1-1	Received from NCI			100	100	AXEL 123	CF
2	1-2	J.J.	45324	54mg	6	94	AXEL 123	CF
3	* 1-2	*Transferred to Dr. A. Smith			* 94	* 0	*AXEL 123	* CF
4		protocol #67890						

Record Date

Record protocol to which drug is transferred

Quantity transferred

Subtract from Balance

Completed protocol

Manufacturer and Lot Number

Recorder's initials

■ **The Drug Accountability Form is used to record drug transfers to an active protocol** (Figure 10).

Figure 10
Drug transferred to an active protocol.

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National Institutes of Health
National Cancer Institute

PAGE NO. 1
CONTROL RECORD X
SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution: Acme Hospital
Protocol No. (NCI): *67890
Drug Name, Dose Form and Strength: Act. 16 Injection 10 mg
Protocol Title: AML
Dispensing Area: Central Pharmacy
Investigator: Dr. A. Smith

Line No.	Date 1989	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward 0 / Balance	Manufacturer and Lot No.	Recorder's Initials
1	*1-2	*Transferred from Dr. T. Thompson			*94	*94	*AXEL 123	*CF
2		protocol #12345						

Record date

Record protocol from which drug is transferred

Quantity transferred

Add to Balance

Active Protocol

Manufacturer and Lot No.

Recorder's Initials

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Expires 6/30/91

National Institutes of Health
National Cancer Institute

Transfer Investigational Drug Form

Investigational Drug Accountability

Investigator Transferring Drug
Dr.

NCI Investigator No.

Date of Transfer

Name of Institution

Street

City

State

Zip Code

This form is to be used for intra-institutional transfer only for the following reasons. (Please check one of the boxes below.)

Completed Protocol ☐

Unused Drug Obtained for Special Exception Protocol ☐

The following drug(s) required for NCI approved protocol(s) are being transferred to NCI approved protocol(s) for:

Investigator _____ No. _____
Investigator Receiving Drug NCI Investigator No.

Received on NCI Protocol No.**	Transferred to NCI Protocol No.	NSC Number	Drug Name	Strength & Formulation	Quantity	Manufacturer and Lot No.

Authorized Signature (Investigator or Designee)

Telephone Number

*Use One Form Per Set Of Investigators.
**No Additional Drug Will Be Supplied For This Protocol No.

All Requested Information MUST Be Supplied In Order For Form To Be Valid.

Return Form To:

Drug Management and Authorization Section
Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment, NCI, NIH
Executive Plaza North, Room 707A
Bethesda, MD 20892

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PAGE NO. _____
CONTROL RECORD ☐
SATELLITE RECORD ☐

Investigational Drug Accountability Record

Name of Institution | Protocol No. (NCI)

Drug Name, Dose Form and Strength

Protocol Title | Dispensing Area

Investigator

Line No.	Date	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1								
2								
3								
4								
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Form approved
OMB No. 0925-0240
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National Institutes of Health
National Cancer Institute

Transfer Investigational Drug Form

Investigational Drug Accountability

Investigator Transferring Drug Dr.	* NCI Investigator No.	Date of Transfer

Name of Institution

Street	City	State	Zip Code

This form is to be used for intra-institutional transfer only for the following reasons. (Please check one of the boxes below.)

Completed Protocol ☐ Unused Drug Obtained for Special Exception Protocol ☐

The following drug(s) required for NCI approved protocol(s) are being transferred to NCI approved protocol(s) for

Investigator _____ * No. _____
Investigator Receiving Drug NCI Investigator No.

Received on NCI Protocol No.**	Transferred to NCI Protocol No.	NSC Number	Drug Name	Strength & Formulation	Quantity	Manufacturer and Lot No.

_____
Authorized Signature (Investigator or Designee)

_____
Telephone Number

Return Form To:

Drug Management and Authorization Section
Investigational Drug Branch
Cancer Therapy Evaluation Program
Division of Cancer Treatment, NCI, NIH
Executive Plaza North, Room 707A
Bethesda, MD 20892

*Use One Form Per Set Of Investigators
**No Additional Drug Will Be Supplied For This Protocol No.

All Requested Information MUST Be Supplied In Order For Form To Be Valid.

NIH-2564
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Investigational Drug Accountability Record 0925-0240:

Drug Accountability Record—

Public reporting burden for each transaction recorded on the record is estimated to average one minute to complete and review the data entered. For new users the burden for each transaction is estimated to average two minutes. If you have comments regarding this burden please send them to Reports Clearance Officer, PHS, 721-H Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, Attention: PRA, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

Transfer Investigational Drug Form—

Public reporting burden for this collection of information is estimated to average four minutes, including the time for reviewing instructions, and completing and reviewing the data entered. If you have comments regarding this burden please send them to Reports Clearance Officer, PHS, 721-H Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, Attention: PRA; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.